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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,631

11/16/2005

Ruihua Chen

60289-USA

7138

7590

10/03/2007

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EXAMINER

MONSHIPOURI, MARYAM

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

10/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/528,631

Applicant(s)

CHEN ET AL.

Examiner

Maryam Monshipouri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 8-12 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 is/are allowed.
- 6) ☐ Claim(s) 1-2, 4, 7 is/are rejected.
- 7) ☒ Claim(s) 5, 6 and 13 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Claims 1-7, 13 are still at issue and are present for examination. Claims 8-12 are withdrawn.

Applicants' arguments filed on 7/24/2007 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4 and 7 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule , does not reasonably provide enablement for fragments thereof having at least 15 nucleotides with no function according to previous office action. In traversal of this rejection applicant argues the following: **(1)** that the specification fully discloses methods to "identify", derivatize or isolate natural or synthetic mutants of SEQ ID NO:1. It is also expected that the skilled artisan would be able to provide or derive polypeptides having SEQ ID NO:2 by means of protein expression. The specification also describes guidance to those skill in the art how to assess encoded proteins that have myosin light chain kinase activity.

(2) A rejection based on lack of enablement is not appropriate where the amount of experimentation to practice the full scope of the claimed invention would have been

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routine, even if extensive. In view of applicant, since as shown above, the methods used to practice the full scope of applicant's invention are routine and even if expensive the pending rejection should be withdrawn.

These arguments were fully considered but were found **unpersuasive**. In response to applicant's **first** and **second** arguments applicant is reminded that in claims 1, 2 and 4, he/she is claiming fragments of for example 20,000 bases total length having only 15 nucleotides of SEQ ID NO:1, which are not necessarily required to maintain any function.

While the examiner agrees that general methods to generate mutants and derivatives of any polypeptide encoding sequence including SEQ ID NO:1 and general methods of assessing the expression products of said mutants and derivatives (if function known) are well established in the prior art she respectfully disagrees with applicant that the instantly claimed invention is fully enabled. Firstly, applicant is reminded that claimed fragments, as written, are not associated with any activity. Secondly, even if they did, current fragments are so broad in scope that some guidance with regards to structural requirements of fragments beyond the 15 nucleotides of SEQ ID NO:1 is required such that said fragments encode products with myosin light chain activity. Applicant is reminded that claimed fragments only require at least 15 nucleotides of SEQ ID NO:1. that means, for example, in the case given above (20,000-15=) 19,985 bases are unknown and can be anything whatsoever. As stated previously, 15 nucleotides is insufficient to encode any products with any function whatsoever. Therefore, it is highly likely that most DNA sequences embraced by claimed fragments

encode products with functions totally different than myosin light chain kinase. Since guidance with regards to other base constituents of claimed fragments is not provided in the specification, generation and screening for fragments with such breadth of scope imposes an undue burden of screening on the skilled artisan. Once again, since the products of claim 1 are not fully enabled recombinant vectors comprising said products (claim 7) are not fully enabled either.

Claims 1-2, 4 and 7 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, according to previous office action.

In traversal of this rejection applicant relies on the above summarized traversal arguments and is the opinion that since applicant has sufficiently enabled the claimed subject matter therefore the written description requirement is also satisfied. However, as explained above, applicant's arguments were unsuccessful to fully enable the claimed invention because the structural information provided are insufficient to fully enable the invention. Additionally, given the breadth of **genus** of fragments claimed, the specification fails to teach what other functions beyond encoding expression products with kinase activity (i.e. a **single species**) should be assessed when screening for claimed fragments. It is true that claims 1-2 have been amended to recite "having kinase activity" but said function recitation in claims 1-2 does not apply to claimed fragments and therefore the rejection remains for the reasons of record.

Again since products of claim 1 are not adequately described either in terms of structure or in terms of function, a vector comprising said products (claim 7) is not adequately described either.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "having" in claims 1-2, 4-5 is unclear. It is unknown whether applicant by using said term means "comprising " or "having a total length of ". Appropriate clarification is required.

Allowable Subject Matter

Claims 5-6, 13 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims for the reasons stated previously.

Claim 3 is allowed for the reasons or record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on Tues.-Fri., from 7:00 a.m to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleene Kerr Bragdon can be reached on (571) 272-0931. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M. Monshipouri

Maryam Monshipouri Ph.D.

Primary Examiner
